

**REMARKS**

The Office Action of December 9, 2008, has been received and reviewed.

Claims 1-38 are currently pending and under consideration in the above-referenced application. Each of claims 1-38 has been rejected.

Reconsideration of the above-referenced application is respectfully requested.

**Rejections under 35 U.S.C. § 103(a)**

Claims 1-38 have been rejected under 35 U.S.C. § 103(a).

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also be “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR* at 1396. That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Stanley in View of Knodle

Claims 1-10, 13-15, and 17-37 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the subject matter taught in U.S. Patent 3,725,658 to Stanley et al. (hereinafter “Stanley”), in view of teachings from U.S. Patent 4,914,720 to Knodle et al. (hereinafter “Knodle”).

Stanley teaches an integral side stream monitoring apparatus that employs luminescence quenching technology for detecting changes in oxygen present in diverted respiratory samples. As evidenced by FIG. 2 of Stanley, a source 27 and detector 28 are positioned on the same side of a transparent tube 24, but are separated by an opaque plate 29. *See* col. 6, lines 63-65; *see also* col. 6, line 55, to col. 7, line 5. The source 27 is oriented toward a first area of an interior surface of a sensor film 25 located within the tube 24, while the detector 28 is oriented toward another area of the interior surface of the sensor film 25. FIG. 2; col. 6, line 55, to col. 7, line 5. This arrangement provides for separation that is intended “to eliminate spurious readings.” Col. 6, lines 63-65.

The teachings of Knodle relate to an infrared carbon dioxide transducer 26 that is configured for assembly with an airway adapter 28, or cuvette, that has been assembled along a breathing tube 32. FIG. 1; col. 8, line 47, to col. 9, line 10. Accordingly, the airway adapter 28 and transducer 26 of Knodle are part of a so-called “mainstream” sensor. The transducer 26 includes an emitter 36, which is a source of infrared radiation, as well as a detector 38. FIGs. 2 and 3; col. 9, lines 11-20. The emitter 36 and detector 38 of the transducer 26 of Knodle face one another, but are spaced apart from each other to accommodate an airway adapter. *Id.* When the transducer 26 is assembled with an airway adapter 28, as shown in FIG. 1 of Knodle, the emitter 36 directs infrared radiation through the airway adapter 28 and into the detector 38. *Id.* The degree to which an intensity of the infrared radiation is decreased corresponds to an amount of carbon dioxide in the respiratory gases passing through the airway adapter. *Id.*

It is respectfully submitted that there are several reasons that a *prima facie* case of obviousness has not been established against any of claims 1-10, 13-15, or 17-37.

First, it is respectfully submitted that neither Stanley nor Knodle teaches or suggests each and every element of several claims of the above-referenced application.

Neither Stanley nor Knodle teaches or suggests a transducer with a source that is oriented toward an exterior surface of a luminescable element. Again, the teachings of Stanley are limited to an apparatus in which a source and detector are oriented toward different areas of the *interior surface* of a sensor film 25 (FIG. 2; col. 6, line 55, to col. 7, line 5), while the teachings of

Knodle relate to a source and detector that are oriented toward one another so that the attenuation of radiation passing therebetween may be quantified.

Moreover, Stanley and Knodle both lack any teaching or suggestion of a transducer with a source and detector that are oriented toward the same area, or to substantially the same location. Rather, the source 27 and detector 28 of Stanley are positioned so as to be oriented toward different areas (which are separated by an opaque plate 29) of a tube 24, not toward the same area of an exterior surface of a luminescable element, as required by amended independent claim 1, or toward substantially the same location, as recited by amended independent claim 36.

The transducer 26 of Knodle is configured to monitor carbon dioxide by directing infrared radiation completely through an airway adapter 28 so that the amount of attenuation of the radiation can be determined to provide an indication of the amount of carbon dioxide in a respiratory sample. Col. 9, lines 11-20. Thus, the emitter 36 and detector 38 of the transducer 26 taught by Knodle are oriented toward each other, not toward an exterior surface of a luminescable element, toward the same area of an exterior surface of a luminescable element, as required by amended independent claim 1, or toward the substantially same location, as recited by amended independent claim 36.

As neither Stanley nor Knodle teaches or suggests a transducer with a source and detector that are positioned adjacent to one another and that are oriented toward the same area of an exterior surface of a luminescable element or toward the substantially the same location, it is respectfully submitted that the combined teachings of these references do not teach or suggest each and every element of amended independent claim 1 or amended independent claim 36.

Therefore, the Office has not established a *prima facie* case of obviousness against amended independent claim 1 or amended independent claim 36, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

Claims 2-35 are each allowable, among other reasons, for depending from independent claim 1, which is allowable.

Claim 37 is allowable, among other reasons, for depending from independent claim 36, which is allowable.

Moreover, neither Stanley nor Knodle teaches or suggests a transducer with a detector that is configured to communicate with a processor configured to increase a signal-to-noise ratio of a signal indicative of an intensity of at least one wavelength of electromagnetic radiation emitted by a luminescable composition, as required by claim 3. The teachings of Stanley regarding signal-to-noise ratios are limited to the recognition that a high ratio is desirable.

Stanley and Knodle also lack any teaching or suggestion of a transducer that includes a detector that is configured to communicate with a processor that operates under different processing protocols depending upon the monitored oxygen concentration, as recited in claim 5.

Claims 6 and 7 are directed to allowable subject matter since Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that comprises a photodiode or a transducer that comprises a PIN silicon photodiode, respectively.

With respect to the subject matter recited in claim 17, neither Stanley nor Knodle teaches or suggests a transducer with a second radiation source that emits at least a calibration wavelength of electromagnetic radiation. The teachings of Stanley are instead limited to calibration of a sensor with gas mixtures including known concentrations of oxygen.

Claim 18, which depends from claim 17, is also allowable since neither Stanley nor Knodle includes any teaching or suggestion of a transducer with a second radiation source that emits calibration radiation that will not cause a luminescable material of a sensor that configured for assembly with the transducer to luminesce.

With respect to the subject matter recited in claims 25-30, even assuming, *arguendo*, that Stanley suggests the desirability of including a temperature control component in a transducer, neither Stanley nor Knodle teaches or suggests a transducer with a heater component that is configured to contact a thermal capacitor upon assembly of the transducer with a respiratory flow component, as recited in claim 25; a transducer with a temperature control component exposed therethrough, as recited in claim 26; a transducer with a heater component that is configured to be biased against a thermal capacitor of a respiratory flow component, as recited in claim 27; a transducer with a heater component that includes a thick film heater, as recited in claim 28; or a transducer with a temperature sensor that senses a temperature of a heater component, a capacitor, or a luminescable composition, as recited in claim 30.

Independent claim 36 is also allowable since neither Stanley nor Knodle teaches or suggests a transducer with a detector that is substantially stable for about eight hours or more. Additionally, Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that is oriented toward an exterior surface of a window of a respiratory flow component to direct radiation directly through a thickness of the window to a luminescable composition adjacent to an opposite, interior surface of the window.

Claim 37, which is allowable for depending from claim 36, is further allowable because Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that “has a stability of about  $\pm 2$  torr over eight hours at an atmospheric oxygen concentration.”

It is, therefore, respectfully submitted that a *prima facie* case of obviousness has not been established against any of claims 1-10, 13-15, and 17-35. Therefore, under 35 U.S.C. § 103(a), the subject matter recited in each of claims 1-10, 13-15, and 17-35 is allowable over the subject matter taught in Stanley and Knodle.

Second, it is respectfully submitted that, without the benefit of hindsight that the claims of the above-referenced application have provided to the Office, there wouldn't have been any apparent reason for one of ordinary skill in the art to combine teachings from Stanley and Knodle in the manner that has been asserted by the Office. Without such knowledge, one of ordinary skill in the art wouldn't have been motivated to combine teachings that relate to the oxygen sensor of Stanley with a pass-through carbon dioxide sensor of Knodle in the manner that has been asserted.

In particular, the claims of the above-referenced application are directed to transducers. As the side stream monitoring apparatus of Stanley does not include a transducer, the Office has relied upon Knodle for its disclosure of a multi-component respiratory sensor that includes a transducer that is configured for assembly with a “mainstream” cuvette. It is respectfully submitted that one of ordinary skill in the art wouldn't have found any apparent reason to add complexity to the integral side stream, luminescence quenching type oxygen monitoring apparatus of Stanley by incorporating various components thereof into a separate transducer and

airway adapter, or cuvette, particularly from a radiation attenuation type carbon dioxide sensor of the type taught in Knodle.

It is further submitted that one of ordinary skill in the art would have understood the inventive effort required to adapt a luminescence quenching type sensor from the context of side stream monitoring, in which very small respiratory samples are used, to a mainstream device, in which monitoring is conducted on a much large sample – all respiratory gases.

Furthermore, one of ordinary skill in the art wouldn't have been motivated to combine teachings from a luminescence quenching apparatus of the type taught in Stanley with teachings that pertain to an infrared sensing device, such as that taught in Knodle. In the luminescent quenching apparatus of Stanley, radiation emitted from a source follows an obstructed path, which terminates at a luminescable material, and different radiation emitted by the luminescable material is sensed by a detector. In contrast, the infrared sensing device of Knodle requires an unobstructed path so that radiation emitted from a source may be sensed by a detector.

Third, it is respectfully submitted that there would have been no reason for one of ordinary skill in the art to have expected that the purported combination of teachings from Stanley and Knodle would have been successful, particularly when the teachings of these references are considered in their entirety, as required by M.P.E.P. § 2141.02. For example, the luminescent material-coated tube, sensor, and detector of Stanley are part of an integral unit; thus, there would be no reason to couple the transducer of Knodle to the apparatus of Stanley. Even assuming, for the sake of argument, that the transducer of Knodle could be coupled to the apparatus of Stanley, the wavelengths that are generated and detected by the source and detector of Knodle's transducer would not excite the luminescent material within the apparatus of Stanley or detect fluorescence from the luminescent material.

Further, the presence of luminescable material on the surfaces of the tube would interfere with the transmission of infrared radiation completely through the tube, as would be required for the transducer taught in Knodle to work with the sample tube of Stanley. Therefore, one of ordinary skill in the art would not have any reason to expect that features from the mainstream

infrared sensor taught in Knodle could be incorporated into the side stream luminescence quenching sensor taught in Stanley.

Stanley, Knodle, and Yafuso

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly unpatentable over the teachings of Stanley, in view of teachings from Knodle and, further, in view of the subject matter taught in U.S. Patent 4,849,172 to Yafuso et al. (hereinafter “Yafuso”).

Yafuso does not remedy the aforementioned deficiencies of Stanley and Knodle. Therefore, claims 11 and 12 are both allowable, among other reasons, for respectively depending directly and indirectly from claim 1, which is allowable.

Stanley, Knodle, and Hauenstein

Claim 16 has been rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over that taught in Stanley, in view of teachings from Knodle and, further, in view of the teachings of U.S. Patent 4,861,727 to Hauenstein et al. (hereinafter “Hauenstein”).

Hauenstein does not remedy the aforementioned deficiencies of Stanley and Knodle. Therefore, claim 16 is allowable, among other reasons, for depending directly from claim 1, which is allowable.

Stanley, Knodle, and Alcala

Independent claim 38 has been rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is allegedly unpatentable over the teachings of Stanley, in view of teachings from Knodle and, further, in view of the teachings of U.S. Patent 5,315,993 to Alcala et al. (hereinafter “Alcala”).

It is respectfully submitted that none of Stanley, Knodle, or Alcala teaches or suggests a transducer with a source and detector that are adjacent to each other and oriented toward substantially the same location, as required by independent claim 38, as amended herein. To

repeat, the teachings of Stanley are limited to an apparatus in which a source and detector are oriented toward different areas on an interior surface of a sensor film 25, while the spaced apart emitter and detector of Knodle are oriented toward each other.

Furthermore, Alcala does not remedy any of the other aforementioned deficiencies of Stanley and Knodle in supporting a *prima facie* case of obviousness against independent claim 38.

It is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 1-38 be withdrawn, and that each of these claims be allowed.

### CONCLUSION

It is respectfully submitted that each of claims 1-38 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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Date: March 9, 2009  
BGP:TH/kso:ec  
Document in ProLaw